3/26/99

K 990687 Pg 1 of 2

510(k) SUMMARY
OLYMPUS HX-5/6-1 Endoscopic Clipping Device

A. Submitter's Name, Address, Phone and Fax Numbers

1. Manufacturer of the subject devices

Name & Address of manufacturer:	Olympus Optical Co., Ltd. 22-2 Nishi-Shinjuku, 1-Chome, Shinjuku-ku, Tokyo 163-8610 Japan
Registration No.:	8010047
Address, Phone and Fax Numbers: of R&D Department, Endoscope Division	2951 Ishikawa-Cho, Hachioji-shi, Tokyo 192-8507 Japan TEL 0426-42-5101 FAX 0426-46-2786

B. Name of Contact Person

Name: Address, Phone and Fax Numbers:	Ms. Laura Storms-Tyler Olympus America Inc. Regulatory Affairs Two Corporate Center Drive Melville, New York 11747-3157 TEL: (516)-844-5688 FAX: (516)-844-5416

C. Device Name, Common Name, Classification Name and Predicate Devices

Device Name:	Olympus HX-5/6-1 Endoscopic Clipping Device Standard Clips MD-59/850 Long Clips MD-858 Short Clips MD-859 MAJ-459 Short Clip
Common Name:	Endoscopic Clipping Device
Classification Name:	Endoscope and accessories
Predicate Device:	Olympus HX-5/6-1 Endoscopic Clipping Device K963160

D. Description of the Device(s)

The HX-5/6-1 Endoscopic Clipping Device is available as a set consisting of the HX-5/6-1 Endoscopic Clipping Device main body and clips.

These clips are attached to the hook when the wire is advanced out of the distal end of the device. Applying tension to the control wire will "seat" a step on the clip onto the distal end of the stainless steel coil. The FEP tube sheath may then be advanced to cover the distal end of the coil and the attached clip. The device may then be inserted through the instrument channel of the appropriate endoscope.

When the device has been advanced to the area of interest, the tube sheath is retracted by moving the tube joint distally until an audible "click" is heard. When the control section slider is pulled proximally, the control wire is tensioned, and the clip is pulled into the clip body (pipe). Due to the shape of the clip itself, when the clip is pulled into the clip pipe, it will initially open wider. As it is pulled in even further, the clip pipe will force the clip arms to close on the target tissue and deploy.

E. Intended Use of the Device(s)

Olympus HX-5/6-1 Endoscopic Clip Fixing Device has been designed for endoscopic clip placement within the gastrointestinal (GI) tract for the purpose of endoscopic marking, hemostasis in the upper GI tract for mucosal/submucosal defects <3cm, bleeding ulcers and arteries <2mm, polyps<1.5cm in diameter, and anchoring to affix jejunal feeding tubes to the wall of the small bowel. This device is not intended for the repair of GI tract.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 26 1999

Ms. Laura Storms-Tyler
Director, Regulatory Affairs
OLYMPUS America, Inc.
Two Corporate Center Drive
Melville, NY 11042-1179

Re: K990687
Olympus HX-5/6-1 Endoscope Clipping Device
Dated: February 25, 1999
Received: March 1, 1999
Regulatory Class: II
21 CFR 876.1500/Procode: 78 FHN
21 CFR 876.4730/Procode: 78 MND

Dear Ms. Laura Storms-Tyler:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number(if known): K990687

Device Name: **Olympus HX-5/6-1 Endoscopic Clipping Device**

Indications for Use:

Olympus HX-5/6-1 Endoscopic Clip Fixing Device has been designed for endoscopic clip placement within the gastrointestinal(GI) tract for the purpose of endoscopic marking, hemostasis in the upper GI tract for mucosal/submucosal defects <3cm, bleeding ulcers and arteries <2mm, polyps <1.5cm in diameter, and anchoring to affix jejunal feeding tubes to the wall of the small bowel. This device is not intended for the repair of GI tract lumenal perforations.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of [illegible]ctive, Abdominal, ENT,
and Radiological Devices
510(k) Number K990687

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

(Optoinal Format 1-2-96)